3761

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors: Jeffrey et al.
For: Breathing Assistance Apparatus
Serial No.: 09/658,551
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Art Unit: 3761
Atty Docket No.: 1171/38910/79

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on December 15, 2000.

Jennifer L. Soukup

TRANSMITTAL OF CERTIFIED COPY
REGARDING CONVENTION CLAIM UNDER 35 U.S.C. §119

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

In completion of Applicant's claim for priority under 35 U.S.C. §119 for United States Patent application, please find enclosed a true copy of the Provisional Specification as filed on 20 September 1999 with an application for Letters Patent number 337950.

It is believed that this completes Applicant's claim for priority and acknowledgment of receipt of this priority document is requested.

Respectfully submitted,

Date:December 15, 2000

By: _____

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Intellectual Property Office of New Zealand

CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 20 September 1999 with an application for Letters Patent number 337950 made by FISHER & PAYKEL LIMITED.

Dated 12 October 2000.

Neville Harris
Commissioner of Patents

COMMISSIONER OF PATENTS, TRADE MARKS & DESIGNS • NEW ZEALAND •

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NEW ZEALAND

PATENTS ACT, 1953

PROVISIONAL SPECIFICATION

BREATHING ASSISTANCE APPARATUS

We, FISHER & PAYKEL LIMITED a company duly incorporated under the laws of New Zealand of 78 Springs Road, East Tamaki, Auckland, New Zealand, do hereby declare this invention to be described in the following statement:

The present invention relates to the use of a pressure regulator in conjunction with a breathing assistance apparatus, particularly though not solely, for regulating the pressure of gases supplied to an infant using a Positive End Expiratory Pressure (PEEP) device.

The use of a medical apparatus to facilitate breathing in mammals is well known in the art. The apparatus may take the form of a simple oxygen mask or tent which supplies oxygen at slightly above atmospheric pressure. Such devices merely assist a person to breath and work with the person's lungs.

Ventilators which operate at high frequency have been suggested in the past. There are two types of high frequency ventilators known in the art. One type, as exemplified by U.S. Pat. No. 2,918,917 (Emerson), employs a reciprocating diaphragm to vibrate a column of gas supplied to a subject. The vibration is in addition to the subject's respiration, natural or artificial, and at a much more rapid rate, for example, from 100 to more than 1500 vibrations per minute. The Emerson apparatus is primarily designed to vibrate the patient's airway and organs associated therewith, although Emerson also recognized that high frequency vibration causes the gas to diffuse more rapidly within the airway and therefore aids the breathing function. However, the Emerson apparatus is incapable of supporting the patient's full ventilation and must be used in conjunction with the patient's spontaneous breathing or with another apparatus which produces artificially induced inhalation and exhalation.

The second type of high frequency ventilator is the jet pulse ventilator as exemplified in U.S. Pat. No. 4,265,237 (Schwanbom et al.). The Schwanbom et al. ventilator produces high frequency, high pressure pulses of air which are capable of fully ventilating a patient. The respiration pulse enters with a pressure of 0.2 bar (209 cm H_2O) to 2.7 bar (2797.2 cm H_2O). This pressure is sufficient to expand the lungs during inspiration. Expiration is caused by the natural compliance of the lungs after the jet of air is stopped. Accordingly, it can be seen that Schwanbom et al must rely on the compliance of the lungs in order to fully ventilate the patient. If the lung compliance is low, greater pressure must be used. Schwanbom et al also supply a source of lower pressure gas for spontaneous breathing by the patient. While such jet pulse ventilators are useful for some applications, they are not generally applicable and their use is limited mostly to

experimental work.

In U.S. Patent No. 4,821,709 (Jensen) an apparatus is disclosed which provides high frequency oscillations in the gases supplied to a patient using a flexible diaphragm. This provides a more practical method of ventilating a patient without spontaneous breathing of the patient, or the need for a separate ventilator. U.S. Patent No. 4,646,733 (Strot et al.) proposes an apparatus for producing high frequency oscillations in gases supplied to a patient using a valve controlling the exhaled gases.

It is an object of the present invention to provide a pressure regulator which goes some way to overcoming the above-mentioned disadvantages, or which will at least provide the public with a useful choice.

Accordingly, in a first aspect, the present invention may be broadly said to consist in a pressure regulating device for use with a breathing assistance apparatus which conveys inhalatory gases to, and removes exhalatory gases from a patient requiring breathing assistance, comprising:

a container which in use includes a body of liquid,

terminal conduit means including proximate and distal ends, said proximate end adapted for connection to breathing assistance apparatus accepting exhalatory gases therefrom, and said distal end submerged in said body of liquid,

such that in use the mean pressure of said inhalatory gases supplied to said patient is determined by the level to which said distal end is submerged in said body of water.

In a second aspect, the present invention may broadly be said to consist in a breathing assistance apparatus for supplying gases to a patient to assist said patient's breathing including: gases supply means adapted to supply gases to said patient, connector means including a plurality of ports adapted to deliver said flow of gases to said patient, inhalatory gases transport means for conveying said flow of gases from said gases supply means to said connector means, exhalatory gases transport means for conveying said patient's exhalations from said connector means, and a pressure regulating device comprising:

a container which in use includes a body of liquid, and

terminal conduit means including proximate and distal ends, said proximate end adapted for connection to said exhalatory gases transport means accepting said patient's

exhalations therefrom, and said distal end submerged in said body of liquid,

such that in use the mean pressure of said inhalatory gases supplied to said patient is determined by the level to which said distal end is submerged in said body of water.

Preferably, said terminal conduit means includes a baffled section which in use is located within said container, whereby in use said baffled section may be adjusted in axial length in predetermined increments.

Alternatively, said terminal conduit means includes a connection means to said container, whereby in use said terminal conduit means may be adjusted in axial position in predetermined increments.

Preferably, said connection means comprises at least one partial ridge on said terminal conduit means and at least one matching partial groove or ridge on said container.

Preferably, said predetermined increments are one half centimetre each.

Preferably, said regulating device further comprises overflow means for regulating the level of said body of liquid with respect to said container to a substantially constant level.

Preferably, said overflow means also includes damping means for filtering any perturbations in said level of said body of water, whereby in use said overflow means regulates the "mean" level of said body of water.

Preferably, said overflow means comprises an outlet from said container which is located at a position which in use is substantially below the level of said body of water, and means for reducing the pressure waves at said outlet produced in use in said body of water by patient's exhalations flowing there-through located at a position which in use is between the level of said body of water and said outlet.

In a third aspect, the present invention may be broadly said to consist in a pressure regulating device for use with a breathing assistance apparatus which conveys inhalatory gases to, and removes exhalatory gases from a patient requiring breathing assistance, comprising:

a container which in use includes a body of liquid, and

terminal conduit means including proximate and distal ends, said proximate end operatively connected to breathing assistance apparatus accepting exhalatory gases therefrom, and said distal end submerged in said body of liquid,

such that in use the resultant bubbling occurring in said body of water produces relatively small controlled perturbations in the pressure of inhalatory gases supplied to a patient.

This invention may also be said broadly to consist in the parts, elements and features referred to or indicated in the specification of the application, individually or collectively, and any or all combinations of any two or more of said parts, elements or features, and where specific integers are mentioned herein which have known equivalents in the art to which this invention relates, such known equivalents are deemed to be incorporated herein as if individually set forth.

The invention consists in the foregoing and also envisages constructions of which the following gives examples.

One preferred form of the present invention will now be described with reference to the accompanying drawings in which;

Figure 1 is a block diagram showing a typical configuration for supplying breathing assistance to a patient,

Figure 2 is a plan view of the first embodiment of the present invention without the lid on,

Figure 3 is a cross-section of the first embodiment of the present invention,

Figure 4 is a side view of the first embodiment of the present invention,

Figure 5 is a side view of the end of the exhalatory conduit which extends into the water chamber according to the first embodiment of the present invention,

Figure 6 is a cross-section of the end of the exhalatory conduit which extends into the water chamber according to the first embodiment of the present invention,

Figure 7 is a plan view of the pressure regulator with the lid on according to the second embodiment of the present invention,

Figure 8 is a side view of the pressure regulator according to the second embodiment of the present invention,

Figure 9 is a cross-section of the pressure regulator at B-B according to the second embodiment of the present invention,

Figure 10 is an alternative side view of the pressure regulator according to the second embodiment of the present invention,

Figure 11 is a frontal view of the end of the exhalatory conduit which extends into the water chamber according to the second embodiment of the present invention,

Figure 12 is a cut-away view of the end of the exhalatory conduit which extends into the water chamber according to the second embodiment of the present invention,

Figure 13 is a bottom view of the end of the exhalatory conduit which extends into the water chamber according to the second embodiment of the present invention,

Figure 14 is a plan view of the lid according to the second embodiment of the present invention,

Figure 15 is a side view of the lid according to the second embodiment of the present invention.

The present invention provides a means of producing the variations or oscillations in the pressure of gases supplied to a patient connected to a positive pressure ventilation device. By submerging the end of the exhalatory conduit into a water column the resulting bubbles generate a semi random variation or ripple in the mean pressure of gases delivered to the patient. In doing so it also provides a simple method of varying the mean pressure of gases supplied to the patient by variation of the level to which the end of the exhalatory conduit is submerged within the water column. In order to keep the mean pressure of gases supplied to the patient constant the level of submergence of the end of the exhalatory conduit must be kept constant and an apparatus for ensuring this occurs is also disclosed.

Referring now to Figure 1 in which a typical application is depicted. A humidified Positive End Expiratory Pressure (PEEP) system is shown in which a patient 119 is receiving humidified and pressurised gases through a nasal mask 128 connected to a inhalatory conduit 121. It should be understood that the present invention, however, is not limited to the delivery of PEEP gases but is also applicable to other types of gases delivery systems. Inhalatory conduit 121 is connected to the outlet 112 of a humidification chamber 110 which contains a volume of water 115. Inspiratory conduit 121 may contain heating means or heater wires 118 which heat the walls of the conduit to ensure a constant humidity profile along the conduit and therefore reduce condensation of humidified gases within the conduit. As the volume of water 115 within humidification chamber 110 is heated, water vapour begins to fill the volume of the chamber above the water's surface

and is passed out of the humidification chamber 110 outlet 112 with the flow of gases (for example air) provided from a gases supply means or blower 118 which enters the chamber 110 through inlet 116.

The humidified gases pass through the inhalatory conduit 121 to the mask 128 attached around the patient's 119 mouth. The excess gases then flow through the exhalatory conduit 130 to a pressure regulator 140.

Pressure Regulator

In the preferred embodiment of the present invention the pressure regulator 134, takes the form of submerging the end of the exhalatory conduit 136 into a column of water 138. Referring now to Figures 2 through to 4, the pressure regulator 134 and associated components are seen in more detail. The exhalatory conduit 130 is attached to the lid 144 of the water chamber 142 via connector 146. It communicates with an adjustable plastic baffle 148 within the container 142. The baffle 148 is surrounded by a cylindrical guide 150 to keep it substantially vertical. The chamber 142 is filled with a body of water 138 up to a predetermined lever 140, preferably higher than the base of the guide 150. It will be appreciated that any appropriate liquid could be used instead of water.

The gases flowing through the exhalatory conduit 130 are discharged into the body of water 138 from a short conduit 136 extending from the baffle 148. This results in a bubbling effect, whereby the gases eventually exit the chamber 142 via the outlet port 152.

It will be appreciated that for control over the mean pressure of supplied gases it is necessary to vary the level of which the short conduit 136 is submerged in the body of water 138. Referring now to Figures 5 and 6, the baffle 148 is constructed such that it may be extended downwards or contracted upward, in a concertina effect, in steps of ½ cm each. This then corresponds to a variation in the pressure of gases delivered to the patient of ½ cm H_2O, which is thought adequate for most applications. In one embodiment, the baffle is adjustable over a range from 4-8 cm H_2O but it will be appreciated that this can be modified to requirements.

Constant Water Level

In the preferred embodiment, the present invention is used in conjunction with a

humidified PEEP respirator. As such, the exhalatory gases will have quite high levels of humidity, some at which will inevitably condense in the body of water 138 in the pressure regulator 134. Thus, over time the volume of water in the water chamber 142 will rise and if unchecked will result in rising pressure of gases supplied to the patient and resultant adverse side effects. To ensure the water level is kept constant the water chamber is provided with an overflow facility 160 seen in Figures 2 to 4. Because of the vigorous bubbling occurring at the top of the body of water a simple lip over which excess liquid can flow would be ineffective. To alleviate the effect of the bubbles, a slot 162 and weir 164 are provided. The width of the slot 162 is chosen such that the surface tension of any bubbles impinging thereon is enough to ensure they do not pass into the overflow passage 166 over the weir 164 and into the detachable tank 168. As a result only changes in the mean water level are acted on by the overflow facility 160. It will be appreciated that due to the low level of condensation the detachable tank 168 may be emptied in use while the respirator continues to operate.

Further embodiments

It will be appreciated that a number of alternative constructions are available to achieve a similar result. Referring now to Figures 7 through to 10, an alternative embodiment of the regulator 134 and associated components is shown in more detail. In order to mitigate the effect of the vigorous bubbling near the top of the chamber 200 a main outlet port 202 from the main chamber 204 is provided at a substantially lower level than where the bubbles would normally be expected to occur. However, the bubbling also causes pressure waves throughout the body of the liquid. These pressure waves would normally be reflected through the main outlet port 202 into the intermediate overflow chamber 206 and therefore result in more water escaping than it is desired. To alleviate the effect of the pressure waves a wave shield 208 is located in an intermediate position between the upper level of the water 210 and the main outlet port 202. This masks the outlet port 202 from the majority of the pressure waves due to the surface bubbling.

This effectively means that the water level in the intermediate chamber 206 is relatively calm and substantially representative of the mean (as opposed to the instantaneous) water level in the main chamber 204. The water level in the intermediate

overflow chamber 206 [illegible] is regulated by an overflow port 212 situated on a raised adjacent platform 214. The overflow port 212 is surrounded by a slightly cylindrical raised partition 216 in order to overcome the effect of any small remaining waves in the intermediate overflow chamber 206.

The water then flows into the detachable overflow chamber 218 which when full may be detached in use and emptied.

It will also be appreciated that the apparatus used to vary the mean water level in the main chamber may take a number of forms.

In a further embodiment the present invention involves the use of rotatable vertically adjustable locking system as part of the conduit extending into the body of water. In this embodiment the level to which the conduit extends into the chamber may be adjusted externally from the regulator and while in use. Referring to Figures 11 to 15, the end of the exhalatory conduit 136 which extends into the column of water 138 includes upon its length a number of radial ridges 220 spaced at ½ cm intervals. The ridges 220 exist only on two opposing quarters of the circumference of the exhalatory conduit 136. This allows it to interact with the lid 222 of the main chamber 204 which also have a set of matching grooves 226 on opposing quarters of its circumference in such a way as to allow vertical adjustment. It will be appreciated that by rotating the exhalatory conduit 136 the ridges 222 may be shifted out of their locking position in the notches 226 into the open channel section of the lid aperture 224 and freely vertically adjusted to a suitable position. Once the position is found the exhalatory conduit 136 may then be rotated back into a locking position where the ridges 222 again mate with the grooves 226.

As with the first embodiment a shielded outlet port is also provided in the lid aperture 152 to allow the exhalatory gases to exit the chamber.

The outlet port shielding allows the main chamber 204 and the overflow chamber 206 to be operated in a position other than horizontal without liquid water being expelled from the outlet port. The outlet port shielding prevents liquid aerosols created by the vigorous bubbling on the surface of the water from being expelled.

DATED THIS 20 DAY OF September 19
A.J. PARK & SON
PER
AGENTS FOR THE APPLICANT

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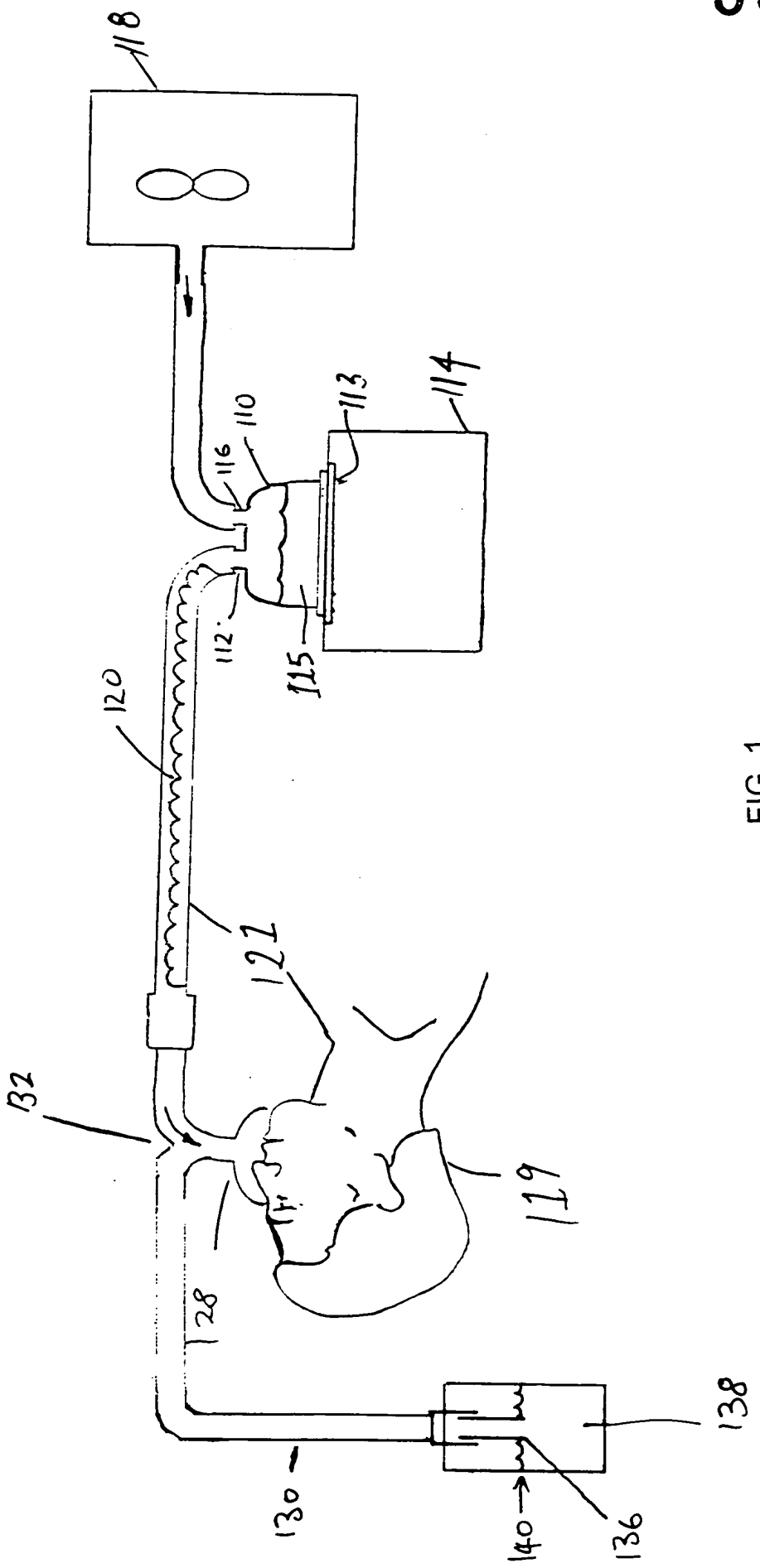

FIG. 1

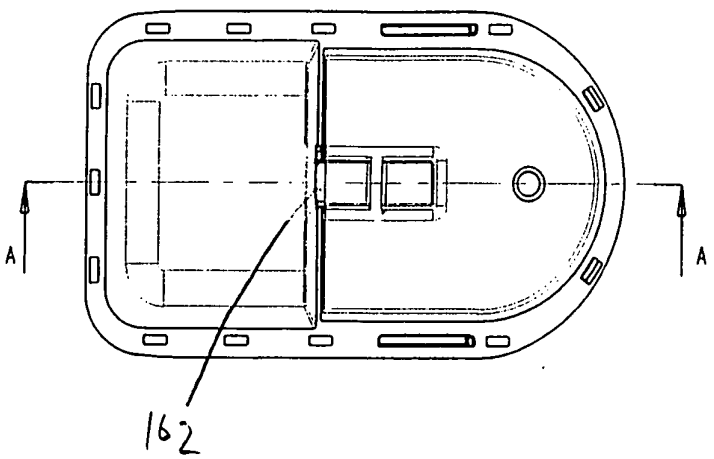

FIG. 2

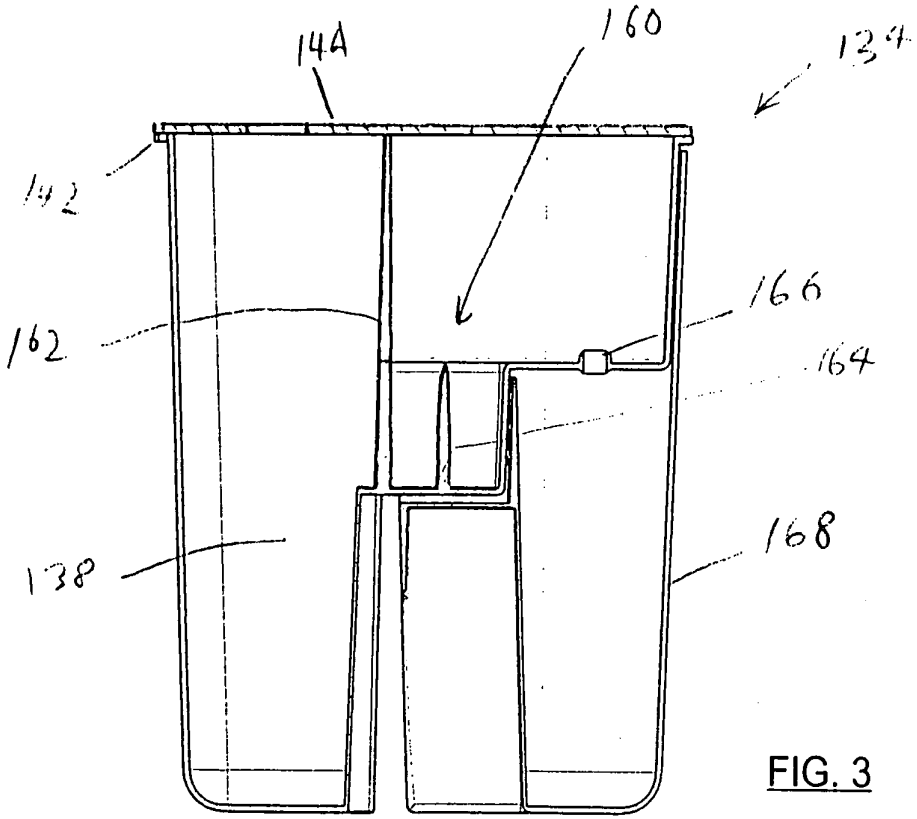

FIG. 3

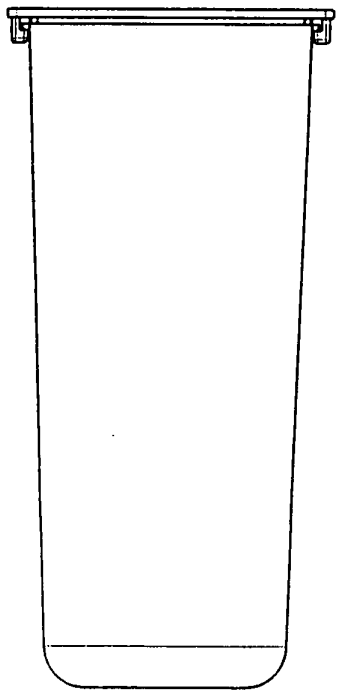

FIG. 4

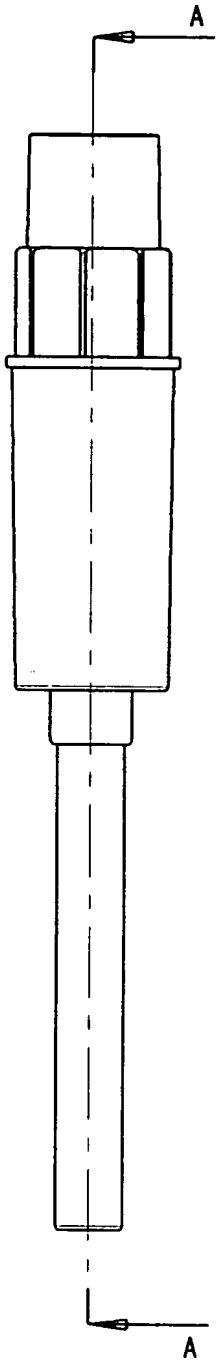

FIG. 5

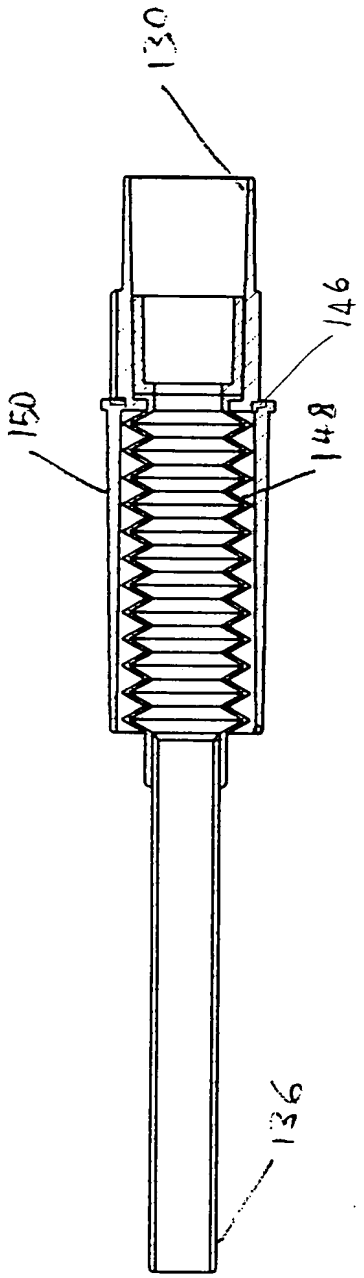

FIG. 6

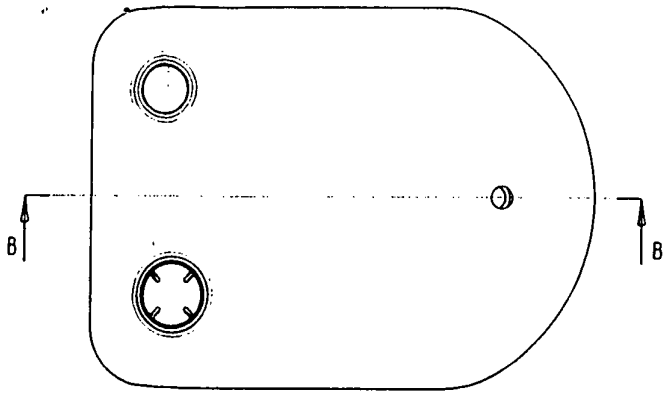

FIG. 7

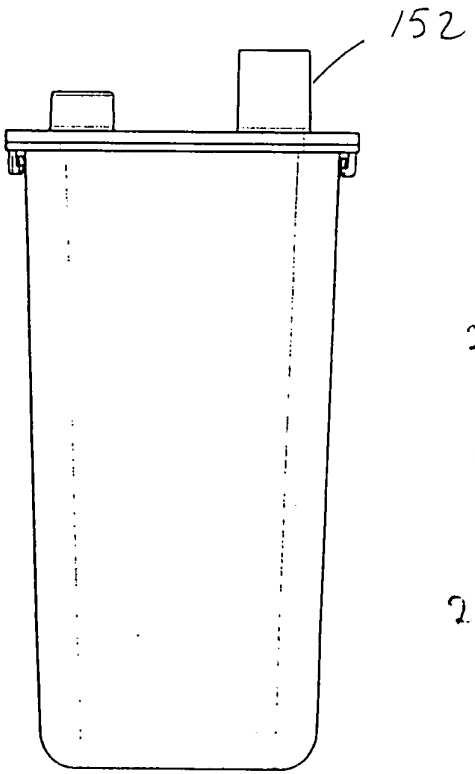

FIG. 8

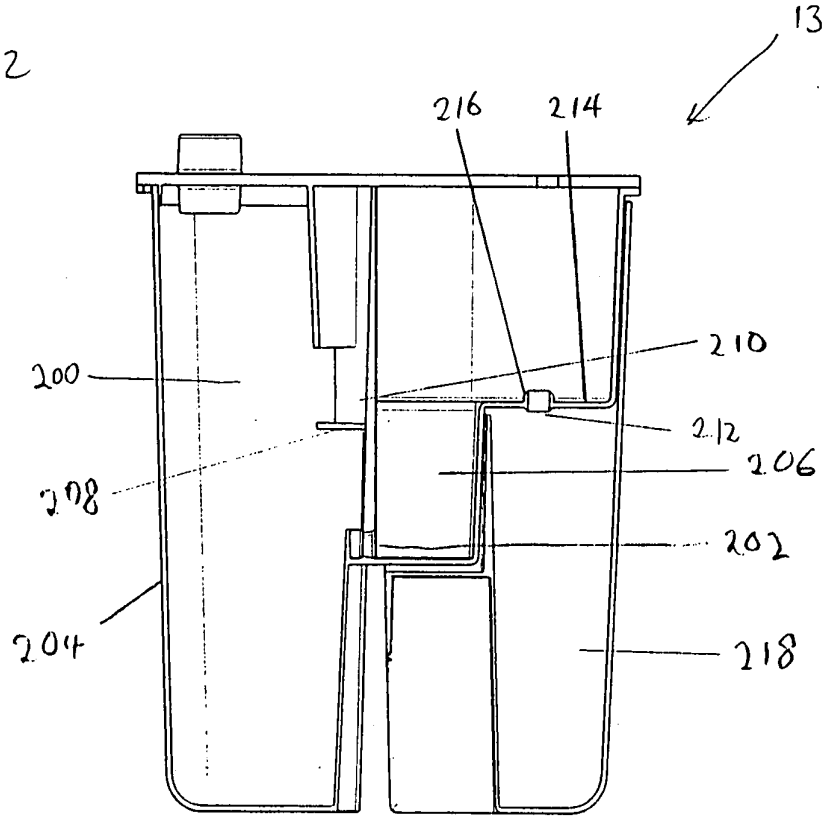

FIG. 9

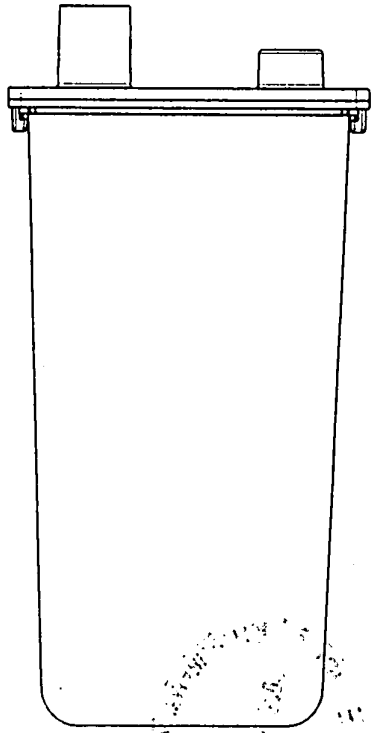

FIG. 10

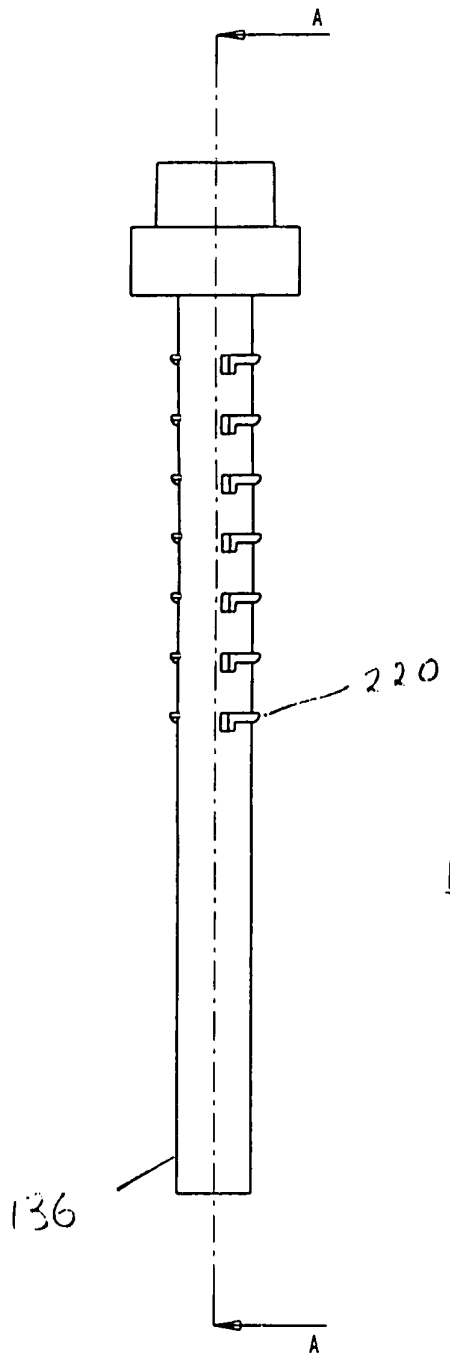

FIG. 11

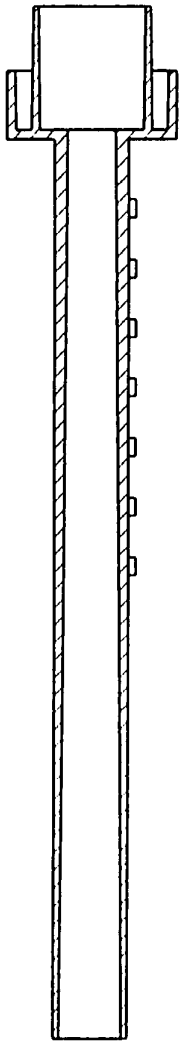

FIG. 12

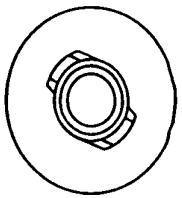

FIG. 13

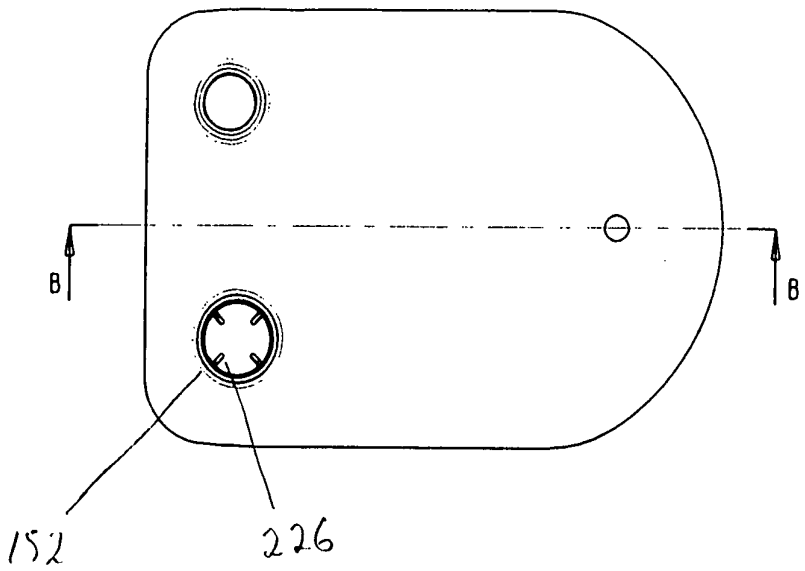

FIG. 14

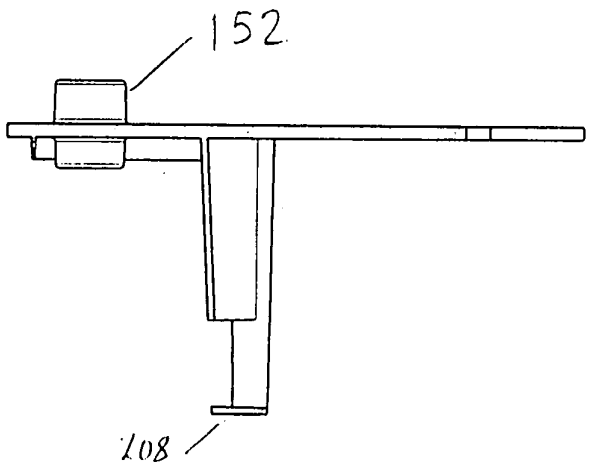

FIG. 15